

REMARKS

Applicants respectfully acknowledge receipt of the Office Action mailed October 15, 2004.

By this amendment, Applicants add new claims 39-43. Thus, claims 25-43 are pending. Of these claims, claims 25 and 33 are independent.

In the Office Action, the Examiner (1) rejected claims 33-38 under 35 U.S.C. §103(a) as being unpatentable over *Castellano et al.* (U.S. Patent No. 5,728,074) in view of *Allen et al.* (U.S. Patent No. 5,837,546) and *Buse et al.* (U.S. Patent No. 6,591,125); and (2) allowed claims 25-32.*

Applicants gratefully acknowledge the Examiner's indication of allowable subject matter in claims 25-34. Based on the foregoing amendments and the following remarks, Applicants traverse each of the above rejections.

I. §103(a) REJECTION OF CLAIMS 33-36

Claims 33-38 stand rejected under 35 U.S.C. §103(a) as being unpatentable over *Castellano*, in view of *Allen et al.* and *Buse et al.* Applicants respectfully traverse the rejection.

To establish a *prima facie* case of obviousness under 35 U.S.C. §103(a), each of three requirements must be met. First, the reference or references, taken alone or

* In the body of the Office Action, claims 33 and 34 are listed as both rejected under 35 U.S.C. §103(a), and as allowed. See Office Action, p. 2, line 8, and p. 5, line 9. However, Applicants believe the listing of claims 33 and 34 as allowed to be a typographical error. Applicants respectfully request that the Examiner clarify the status of claims 33 and 34.

combined, must teach or suggest each and every element recited in the claims. Second, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to combine the references in a manner resulting in the claimed invention. Third, a reasonable expectation of success must exist. Moreover, each of the three requirements must "be found in the prior art, and not be based on applicant's disclosure." See M.P.E.P. §2143, 8th ed., February 2003.

Amended claim 33 recites, *inter alia*:

A method of using a test strip to test a blood sample, said test strip including a sample chamber, a working electrode, a counter electrode, a pair of fill-detect electrodes, and an auto-on conductor

The Examiner admits that "*Castellano* is silent as to the details of the meter entering the active mode from the sleep mode and detecting the blood sample in the chamber and the current measurement." *Office Action*, p. 2, ll. 17-19. In order to cure the deficiency, the Examiner asserts *Allen et al.* teaches "the meter detects an auto-on current through the conductor 22, 36 and responsively enters an active mode from sleep mode." *Office Action*, p. 2, ll. 20-22.

However, in *Allen et al.* the electrodes 22 and 36 are disposed on the housing 18 and not on the reagent strip 20. See *Allen et al.*, col. 8, ll. 25-30, and FIG. 3. Thus, contrary to the Examiner's assertions, *Allen et al.* does not teach "a test strip...including...an auto-on conductor," as recited in claim 33. Further, *Buse et al.* is not relied upon to teach, and does not teach "a test strip...including...an auto-on conductor."

Thus, for at least these reasons, the invention of claim 33 is not taught by *Castellano et al.*, *Allen et al.*, and *Buse et al.*, whether taken alone or in combination. Accordingly, Applicants respectfully request that the rejection of claim 33 under 35 U.S.C. §103(a) be withdrawn and the claim allowed.

In addition, claim 37 recites, *inter alia*, “if said drop-detect current reaches a drop-detect threshold value within a predetermined time period, said meter starts an incubation time period,” and claim 38 recites “said meter applies said assay voltage after said incubation time period.” The Examiner asserts “Castellano...fails to teach the meter starting an incubation time period...however, Buse teaches that the sample may be incubated for a period of time.” *Office Action*, p. 5, ll. 3-4.

The Examiner cites col. 52, line 65 – col. 53, line 16 of *Buse et al.* to support this proposition. However, Applicants can find no teaching in *Buse et al.* describing “if said drop-detect current reaches a drop-detect threshold value within a predetermined time period, said meter starts an incubation time period,” as recited in claim 37, or describing “said meter applies said assay voltage after said incubation time period,” as recited in claim 38, either in the cited portions thereof (col. 52, line 65 – col. 53, line 16), or anywhere else. Accordingly, claims 37 and 38 are distinguished from *Castellano et al.*, *Allen et al.*, and *Buse et al.*, for at least these additional reasons, and Applicants respectfully request that the rejection of these claims be withdrawn and the claims allowed.

New claims 39-43 depend from claim 33. As explained, claim 33 is distinguished from *Castellano*, in view of *Allen et al.* and *Buse et al.*, whether taken alone or in combination. Accordingly, claims 39-43 are also distinguished from *Castellano et al.*,

Allen et al., and *Buse et al.*, for at least the same reasons as claim 33. Applicants respectfully request that new claims 39-43 be allowed along with claims 33-38.

Moreover, new claim 39 recites, *inter alia*, "said meter validating said working and counter electrodes by applying a first validation voltage between said working and counter electrodes," and new claim 40 recites "said meter validating said fill-detect electrodes by applying a second validation voltage between said fill-detect electrodes, while said first validation voltage is applied between said working and counter electrodes." The Examiner admits "with regards to claims 25-34, the prior art of record fails to teach...wherein a meter validates the fill-detect electrodes...by applying a second validation voltage between the fill-detect electrodes while a first validation voltage is applied between the working and counter electrodes." *Office Action*, p. 5, ll. 11-16. Accordingly, new claims 39 and 40 are allowable for at least the same reasons as claims 25-34.

II. CONCLUSION

Applicants respectfully submit that independent claims 25 and 33 are in condition for allowance. In addition, claims 26-32 and 34-43 are in condition for allowance at least due to their dependence from claims 25 and 33 respectively.

The Office Action contains characterizations of the claims and the related art with which Applicants do not necessarily agree. Unless expressly noted otherwise, Applicants decline to subscribe to any statement or characterization in the Office Action.

In view of the foregoing amendments and remarks, Applicants respectfully request reconsideration and reexamination of this application and the timely allowance of the pending claims.

Please grant any extensions of time required to enter this response and charge any additional required fees to our deposit account 06-0916.

Respectfully submitted,

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